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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/180,209	12/22/1999	MIHAIL N. KARPUSAS	B189	6529

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/180,209

**Applicant(s)**

KARPUSAS ET AL.

**Examiner**

Marjorie A. Moran

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39,42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39,42 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/15/04</u> . | 6) <input type="checkbox"/> Other: _____  |

All rejections and objections not reiterated below are hereby withdrawn. Claims 39 and 42-43 are pending.

***Information Disclosure Statement***

The IDS filed 3/15/04 has been considered in full.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.  
This application currently names joint inventors.

In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant's arguments filed 3/2/04 have been fully considered but they are not persuasive for the reasons set forth below.

Claims 39 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over STALEY (Comp. Usage Mater. Educ. Proc. Symp. (1985), pp. 113-122), with support from LESK et al. (Methods in Enzymology (1985) vol. 115, pp. 381-390).

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STALEY teaches a computer with a memory and color monitor (display screen), wherein the computer comprises a program (instructions) for displaying a 3D representation of a molecule using crystallographic coordinates (pp. 113 and 118-119). The crystal coordinates recited in the claims do not functionally interact with the computer or the program stored therein; i.e. neither the computer nor the program is structurally or functionally changed by the coordinates, therefore the coordinates are nonfunctional descriptive material. See also the definition set forth in MPEP 2106, reiterated below for applicant's convenience. It is noted that where a claim recites nonfunctional descriptive material which is not functionally related to the substrate on which it is stored, the nonfunctional descriptive material is considered, but is not entitled to patentable weight; i.e. as the structure coordinates do not functionally interact with the computer claimed, they are nonfunctional descriptive material, and therefore do not distinguish the claimed invention from the prior art of STALEY.

MPEP 2106.IV.B.1(b) defines Nonfunctional Descriptive Material as:

"Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or

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composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture.”

With regard to analysis under 35 USC 103, MPEP 2106.VI states: “Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or

- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.”

In response to applicant's argument that in re Gulack is “of no consequence”, the examiner maintains that as analysis of non-functional descriptive material rests at least in part on the analysis and decision of the Gulack case, as set forth in the MPEP, above, in re Gulack is quite relevant. The digits on the ring in in re Gulack were determined to be functional descriptive material as they functionally interacted with the substrate and as the particular sequence of digits and the deviation thereof were not suggested by the prior art; i.e. the “algorithm” could not be performed with just “any” list of numbers. In contrast, the computer and program of the instant claims CAN be used to produce a three-dimensional representation of the binding site of *any* protein for which structure coordinates are known. For support that a computer program for three-dimensional representation can be used with any known set of structure coordinates, applicant is directed to the prior art of LESK et al. (Methods in Enzymology (1985) vol. 115, pp. 381-390). LESK teaches that three-dimensional representations of a variety of proteins can be generated on a computer using the same set of instructions, but different input/data coordinates. It is noted that LESK does NOT teach that the computer or program is changed in any way upon reading of data input files (see e.g. pp. 382-383), thus the multiplicity of arguments that the structure coordinates themselves are functional descriptive material are not persuasive.

In response to the argument that the claims are directed to a “special purpose” computer, it is admitted that the claims are, in fact, directed to a computer which comprises a program for three-dimensional representation of a protein, or portion thereof. The program does

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appear to interact functionally with the computer to produce a 3-D representation, thus the claims are distinguished from a "general-purpose" computer, thus applicant's arguments that the claimed computer is not a "general-purpose" computer are convincing. However, the prior art of STALEY is also directed to a "special-purpose" computer, which comprises instructions (i.e. a program) for producing three-dimensional representation of proteins. The program of the instant claims is not limited to any particular steps or list of instructions, nor do the claims recite any particular algorithm to produce the 3-D representation, thus the program, while distinguishing the claimed computer from a "general-purpose" one, does not distinguish the claimed device from that of STALEY, and STALEY makes obvious the claimed device.

Claims 39 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over OSSLUND (US 5581476, filed 1/28/1993).

OSSLUND teaches a Silicon Graphics 320 VGX computer comprising a display screen, wherein the computer comprises a program for displaying a 3D representation of a molecule using crystallographic coordinates (col. 6, line 23-col. 7, line 2). OSSLUND specifically teaches that his program may be one which is commercially available, e.g. Insight II, and may be used with different and/or altered sets of coordinates (col. 6, lines 23-66). It is noted that where a claim recites nonfunctional descriptive material which is not functionally related to the substrate on which it is stored, the nonfunctional descriptive material is considered, but is not entitled to patentable weight; i.e. as the structure coordinates do not functionally interact with the computer claimed, they are nonfunctional descriptive material, as previously set forth and reiterated above, and therefore do not distinguish the claimed invention from the prior art of OSSLUND.

Applicant's arguments are addressed above. Briefly, with respect to OSSLUND, it is noted that OSSLUND specifically teaches that different coordinates or structure sets may be

input into a known, and/or commercially available program in order to produce a 3-D representation of a protein, thus providing support that his computer and program may be used with *any* set of coordinates to produce a 3-D representation. As OSSLUND teaches a computer and program for producing a 3-D representation of a protein, or portion thereof, OSSLUND teaches a "special-purpose" computer which renders obvious the claimed invention.

Claims 39 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over STALEY (Comp. Usage Mater. Educ. Proc. Symp. (1985), pp. 113-122) in view of YELLIN et al. (US 6,340,459, filed 12/1/1995).

The claims recite computers for 3D display of a molecule, wherein the computers comprise a computer readable medium, a computer screen, a program with instructions to produce a 3D representation, and a computer-readable medium comprising structural coordinate data. Claim 39 further limits the computer readable medium to comprise data for structure coordinates of CD40 ligand (CD40L) amino acids 143, 203, 207, and 145. Claim 42 limits the computer readable medium to comprise data for structure coordinates for CD40L amino acids according to Table 1. Claim 43 limits the computer readable medium to comprise data for structure coordinates of CD40L amino acids 127-131, 135, 136, 141-146, 178, 180, 185-188, 190-192, 197-204, 207, 209, 211, 217-220, 230-232, 240-243, 245, 247-253.

STALEY teaches a computer for 3D display of crystal structures, comprising a memory (computer readable medium) and a monitor (screen), as set forth above. STALEY does not teach that his memory comprises the coordinates recited in the claims.

YELLIN teaches structural coordinates for residues 116-261 of human CD40L (Figure 17 and col. 5), and teaches that such coordinates may be input into a known computer program and modeled using computer modeling software (col. 11, lines 33-56).



It would have been obvious to one of ordinary skill in the art at the time of invention to have included structure coordinates for residues 116-261 of human CD40L, as taught by YELLIN, in the computer readable medium in the computer of STALEY where the motivation would have been to use the computer and program of STALEY to project a 3D representation of a putative receptor binding site of CD40L, as suggested by the tertiary structures and 3D alignments taught by PEITSCH (Fig's 2, 4 and 5) and the computer modeling of YELLIN. One skilled in the art would reasonably have expected success in including the structure coordinates for human CD40L in the computer readable medium and computer of STALEY because YELLIN teaches that structure coordinates for human CD40L were known and could be used for 3D representation (col. 11, lines 36-40), and STALEY teaches that his computer can be used to visualize and display 3D representations of crystallized molecules.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

mam

*Marjorie A. Moran*  
*5/25/04*